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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,975	11/21/2001	Hiroko Abe	13558-004001 / PH-1407US	1698
20985	7590	10/15/2004	EXAMINER STEADMAN, DAVID J	
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/989,975	Applicant(s) ABE ET AL.	
	Examiner David J Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 17-21,25-27,29-31,34-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,22-24,28,32,33 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 1-38 are pending in the application.
- [2] Applicants' amendment to the claims, filed August 27, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicants' amendment to the specification, filed August 27, 2004, is acknowledged.
- [4] Applicants' arguments filed on August 27, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.
- [6] Claims 17-21, 25-27, 29-31, 34-36, and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification/Informalities

- [7] In view of the amendment to the specification, the objection to the specification as set forth at item [6] of the Office action mailed February 24, 2004, is withdrawn.

Claim Objections

[8] In view of the amendment to the claims, the objections to claims 14, 16, 22, and 33 as set forth at items [7] and [8] of the Office action mailed February 24, 2004, are withdrawn.

[9] Claim 3 is objected to as reciting non-elected subject matter, *i.e.*, SEQ ID NO:2. It is suggested that applicants amend the claim such that it no longer recites non-elected subject matter.

[10] Claim 7 is grammatically incorrect in the recitation of "the peptide or a polypeptide coding sequence." It is suggested that applicants replace the term with, for example, "the peptide or polypeptide coding sequence."

Claim Rejections - 35 USC § 112, Second Paragraph

[11] In view of the amendment to the claims, the rejection of claim 6 for lacking antecedent basis in the recitation of "the enzyme" is withdrawn.

[12] In view of the amendment to the claims, the rejection of claim 7 for lacking antecedent basis in the recitation of "the Pir (protein internal repeat) protein motif coding sequence" is withdrawn.

[13] In view of the amendment to the claims, the rejection of claim 10 as being confusing in the recitation of "the expression vector comprises a yeast expression vector" is withdrawn.

[14] In view of the amendment to the claims, the rejection of claim 12 (claim 28 dependent therefrom) as being confusing in the recitation of "the host cell...
...comprising a yeast host cell" is withdrawn.

[15] In view of the amendment to the claims, the rejection of claims 14 (claims 32-33 dependent therefrom), 15-16, 22 (claims 24 dependent therefrom), 23, and 28 as being indefinite in the recitation of "useful protein" is withdrawn.

[16] In view of the amendment to the claims, the rejection of claims 14 (claim 15 and 32-33 dependent therefrom), 16, and 22 (claims 23-24 dependent therefrom) as being confusing in the recitation of "a protein comprising an amino acid derived from an amino acid sequence" is withdrawn.

[17] In view of the amendment to the claims, the rejection of claim 24 as being confusing in the recitation of "the microorganism comprises a yeast" is withdrawn.

[18] In view of the amendment to the claims, the rejection of claims 28 and 33 as being confusing in that the claims are drawn to methods for producing an immobilized enzyme is withdrawn.

[19] The rejection of Claim(s) 1-2, 5-16, 22-24, 28, 32-33, and 37 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for the reasons of record as set forth at items [9], [10], [13], and [16] of the Office action mailed February 24, 2004 and the reasons stated below.

[a] In view of applicants' amendment to the claims, claim 1 (claims 2-7 dependent therefrom), 8 (claims 9-10 and 32-33 dependent therefrom), 11 (claims 12-13 and 28 dependent therefrom), 14 (claim 15 and 32-33 dependent therefrom), 16, 22 (claims 23-24 dependent therefrom), and 37 are indefinite in the recitation of "a GAP promoter domain." Neither the specification nor the claims define the meaning of the term "GAP

promoter domain” and it is unclear as to the scope of nucleic acids that are meant to be encompassed by the term. The specification fails to teach which identifying characteristics distinguish “a GAP promoter domain” from any other promoter domain. In the absence of any identifying characteristics of a “GAP promoter,” the examiner has interpreted the term in accordance with MPEP 2111 to encompass any promoter sequence. It is suggested that applicants clearly identify the intended promoter sequence by, for example, the use of a sequence identifier.

It is noted that the specification cites a reference allegedly describing a “GAP promoter” (see p. 29, top of the specification). As this reference is pertinent to the instant rejection, the examiner requests that applicants provide a full citation of this reference in order to locate the cited reference.

[b] The rejection of claims 1 (claims 5-6 dependent therefrom), 2, 7, 8 (claims 9-10 and 32-33 dependent therefrom), 11 (claims 12-13 and 28 dependent therefrom), and 37 as being indefinite in the recitation of “a yeast Pir (protein internal repeat) cell wall protein coding sequence”, “a Pir (protein internal repeat) motif coding sequence”, or “a yeast cell wall protein coding sequence” is maintained.

[c] The rejection of claim 9 (claim 10 dependent therefrom) as being confusing in the recitation of “expression cassette... comprising an expression vector” is maintained.

[d] The rejection of claims 13 and 22 (claim 23 dependent therefrom) as being unclear in the recitation of “host cell... comprising a yeast cell wall” (claim 13) and “microorganism comprising a yeast cell wall” is maintained.

[20] RESPONSE TO ARGUMENT: Applicants argue the rejection has been overcome by amendment. Applicants' argument is not found persuasive.

Regarding parts [b] and [d], it is noted that the amendment fails to clarify the meaning of the claims. It is suggested that applicants review the rejection as set forth at items [10] and [16] of the Office action mailed February 24, 2004. Regarding part [c], while applicant has amended claim 9, the claim remains confusing. It is suggested that, for example, applicants delete "comprising an expression vector" at the end of the claim.

Claim Rejections - 35 USC § 112, First Paragraph

[21] The written description rejection of claims 1-16, 22-24, 28, 32-33, and 37 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [21] of the Office action mailed February 24, 2004 and for the reasons stated below.

[22] RESPONSE TO ARGUMENT: Applicants argue the claims should not be limited to a specific protein species as applicants are entitled to specifically disclosed embodiments and broader claims that are supported by the specification. Applicants argue the broad nature of the chimeric proteins that can be produced demonstrates written description of a broad genus. Applicants' argument is not found persuasive.

Although not expressly stated, it would appear that applicants argue that the peptide, polypeptide, or enzyme coding sequence of the chimeric nucleic acid sequence that is fused to the Pir cell wall protein coding sequence is a non-essential or non-critical element of the claimed invention. However, it is not clear from applicants' arguments as

to whether the peptide, polypeptide, or enzyme coding sequence of the chimeric nucleic acid sequence is meant to be an essential or non-essential element of the claimed invention. Applicants' clarification in this matter is requested. If these elements are non-essential or non-critical to the claimed invention, the examiner agrees with applicants' argument. However, it should be noted that the genus of GAP promoter domains and the genus of yeast Pir cell wall protein coding sequences *are* essential, critical elements of the claimed invention and, as stated in a previous Office action, encompass a widely variant genus including mutants and variants of known GAP promoter domains and yeast Pir cell wall protein coding sequences. It should be noted that applicants do not dispute this assertion by the examiner. As such, the genus of GAP promoter domains and the genus of yeast Pir cell wall protein coding sequences are not fully described by the instant specification. See MPEP 2163. Moreover, it is noted that the CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: "[i]n claims to genetic material, however a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA", without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus". Similarly with the claimed genus of GAP promoter domains and the genus of yeast Pir cell wall protein coding sequences the functional definition of the genus (even if one were to loosely

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construe "cell wall protein" as indicating a function) does not provide any structural information commonly possessed by members of the genus which distinguish the nucleic acid species within the genus from other nucleic acids such that one can visualize or recognize the identity of the members of the genus.

[23] The scope of enablement rejection of claims 1-16, 22-24, 28, 32-33, and 37 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [22] of the Office action mailed February 24, 2004 and for the reasons stated below.

[24] RESPONSE TO ARGUMENT: Applicants argue a "yeast Pir cell wall protein" has a specific, art-recognized structure and function and that the claimed methods and nucleic acids are applicable to a wide and diverse range of polypeptides and peptides. Applicants' argument is not found persuasive.

Regarding the peptide, protein, or enzyme coding sequence moiety of the chimeric nucleic acid, as stated above, if these elements are non-essential or non-critical to the claimed invention, the examiner agrees with applicants' argument that any peptide, protein, or enzyme coding sequence could be incorporated into the chimeric nucleic acid without undue experimentation. As stated above, applicants' clarification as to whether the peptide, protein, or enzyme coding sequence is meant to be an essential or critical element of the claimed invention is requested. Even if the peptide, protein, or enzyme coding sequence is a non-essential, non-critical element, the examiner disagrees with applicants' assertion that a "yeast Pir cell wall protein" has a specific, art-recognized structure and function, particularly as the claims broadly encompass nucleic

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acids encoding mutants and variants of a yeast Pir cell wall protein coding sequence.

Thus the term "yeast Pir cell wall protein" essentially encompasses any Pir cell wall protein coding sequence. Further, the claims broadly encompass any GAP promoter domain, including mutants and variants thereof. The claims are not so limited to a yeast Pir cell wall protein coding sequence or a GAP promoter domain having "a specific structure... ..and a specific function known in the art" as asserted by applicants. Thus, at least in view of the reasons set forth in the analysis of the Factors of *In re Wands* (see pp. 11-14 of the Office action mailed February 24, 2004), the specification does not enable the full scope of claimed nucleic acids and methods.

Claim Rejections - 35 USC § 102

[25] The rejection of claim(s) 1-2, 4, and 7 under 35 U.S.C. 102(b) as being anticipated by Moukadiri et al. (*J Bacteriol* 181:4741-4745; cited by applicants in the IDS filed May 06, 2002) is maintained for the reasons of record as set forth at item [23] of the Office action mailed February 24, 2004 and for the reasons stated below.

[26] RESPONSE TO ARGUMENT: Applicants argue Moukadiri et al. do not teach all limitations of the claims, e.g., an enzyme or a GAP promoter. Applicants' argument is not found persuasive.

It is noted that the chimieric nucleic acid of claims 1-2, 4, and 7 is not limited to comprising an enzyme-coding sequence. Further, as stated above, the term "GAP promoter" is indefinite and the specification and claims fail to define the scope of promoters that are intended to encompassed by the term. As such, in accordance with

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MPEP 2111, the examiner has interpreted the term "GAP promoter" to encompass the promoter incorporated into the expression vector of Moukadiri et al. Thus, Moukadiri et al. anticipates claims 1-2, 4, and 7.

[27] The rejection of claim(s) 1-2, 4-16, 22-24, 28, 32-33, and 37 under 35 U.S.C. 102(b) as being anticipated by Matilla et al. (*Glycobiol* 6:851-859; cited by applicants in the IDS filed June 10, 2002) as evidenced by Moukadiri et al. is maintained for the reasons of record as set forth at item [24] of the Office action mailed February 24, 2004 and for the reasons stated below.

[28] RESPONSE TO ARGUMENT: Applicants argue Matilla et al. as evidenced by Moukadiri et al. do not teach all limitations of the claims, e.g., a GAP promoter. Applicants' argument is not found persuasive.

As stated above, the term "GAP promoter" is indefinite and the specification and claims fail to define the scope of promoters that are intended to encompass by the term. As such, in accordance with MPEP 2111, the examiner has interpreted the term "GAP promoter" to encompass the promoter incorporated into the expression vector of Matilla et al. Thus, Matilla et al. anticipates claims 1-2, 4-16, 22-24, 28, 32-33, and 37.

Claim Rejections - 35 USC § 103

[29] The rejection of claim(s) 1-16, 22-24, 28, 32-33, and 37 under 35 U.S.C. 103(a) as being unpatentable over Matilla et al. in view of Moukadiri et al., Toh-e et al. (*Yeast* 9:481-489; cited by applicants in the IDS filed June 10, 2002), and Mrsa (*Yeast* 15:813-820; cited by applicants in the IDS filed June 10, 2002) is maintained for the reasons of

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record as set forth at item [25] of the Office action mailed February 24, 2004 and for the reasons stated below.

[30] RESPONSE TO ARGUMENT: Applicants argue the combination of references does not teach all limitations of the claims, *e.g.*, a GAP promoter. Applicants' argument is not found persuasive.

As stated above, the term "GAP promoter" is indefinite and the specification and claims fail to define the scope of promoters that are intended to encompass by the term. As such, in accordance with MPEP 2111, the examiner has interpreted the term "GAP promoter" to encompass the promoter incorporated into the expression vectors of the cited references. Thus, in view of the combination of references, claims 1-16, 22-24, 28, 32-33, and 37 would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

[31] Status of the claims:

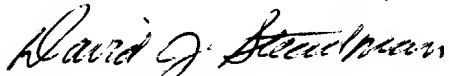
- Claims 1-38 are pending.
- Claims 17-21, 25-27, 29-31, 34-36, and 38 are withdrawn from consideration.
- Claims 1-16, 22-24, 28, 32-33, and 37 are rejected.
- No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.



David J. Steadman, Ph.D.

Primary Examiner

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10-13-04